

**Notice of Allowability**

Application No.

09/754,347

Applicant(s)

GELBER ET AL.

Examiner

Jean C. Witz

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to RCE filed 6/30/03.
2. ☒ The allowed claim(s) is/are 116,135 and 139-142.
3. ☐ The drawings filed on \_\_\_\_\_ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All   b) ☐ Some\*   c) ☐ None   of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date \_\_\_\_\_
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

Jean C. Witz  
Primary Examiner  
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## **DETAILED ACTION**

### ***Election/Restrictions***

1. This application contains claims directed to the following patentably distinct species of the claimed invention:

The species of the second nutraceutical are a bioflavonoid or plant extract containing same, ascorbic acid and pharmaceutically effective salts and derivatives thereof, garlic and extracts thereof, green tea and extracts thereof, Astragalus, zinc and effective salts thereof, Echinacea, Goldenseal and milk thistle or an extract thereof.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 116 –118 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

2. During a telephone conversation with Thomas Powers on March 1, 2004, an election was made without traverse to prosecute the species of Goldenseal.

#### **EXAMINER'S AMENDMENT**

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Thomas Powers on March 2, 2004.

The application has been amended as follows:

IN THE CLAIMS:

Claim 116 has been amended to read:

116. A medicinal composition for treating at least one ailment or symptom caused by an immune response consisting of:

- a pharmaceutical, wherein said pharmaceutical is an antihistamine, alone or in combination with a decongestant;

- a first nutraceutical, said first nutraceutical consisting of an anti-inflammatory agent, said anti-inflammatory agent being stinging nettle or an extract thereof;

- a second nutraceutical selected from the group consisting of Goldenseal, Astragalus, and mixtures thereof; and

- a pharmaceutically acceptable carrier.

Claims 119-134 have been cancelled.

Claim 135 has been amended to read:

135. The medicinal composition of claim 116 wherein the second nutraceutical is Astragalus.

Claims 136-138 have been cancelled.

Claim 139 has been amended to read:

139. The medicinal composition of claim 116 wherein the second nutraceutical is Goldenseal.

Claims 140-142 have been amended to read:

140. The medicinal composition of claim 116, wherein the medicinal composition contains 50 to 1000 mg of powdered stinging nettle.

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141. The medicinal composition of claim 135, wherein the medicinal composition contains 50 to 1000 mg of powdered stinging nettle.

142. The medicinal composition of claim 139, wherein the medicinal composition contains 50 to 1000 mg of powdered stinging nettle.

2. The following is an examiner's statement of reasons for allowance:

Upon election of the species of Goldenseal, a search of the prior art provided no disclosure and therefore no motivation to include Goldenseal with a composition consisting of an antihistamine, optionally in combination with a decongestant, and stinging nettle or an extract thereof. The next species searched was Astragalus, and again, no disclosure and therefore no motivation was found to include Astragalus in a composition consisting of an antihistamine, optionally in combination with a decongestant, and stinging nettle or an extract thereof. However, a search of the species zinc and effective salts thereof resulted in a prima facie case of obviousness for the following reasons.

Prior art references of record (Wiersma (5,948,414), Hamel et al. (4,662,880), Ayer et al. (4,810,502) and Weinstein (6,270,796)) all disclose multiple variations and combinations of conventional anti-histamines and conventional decongestants for treatment of rhinitis from allergies and colds. These references are essentially duplicative. Newly cited reference to Mittman discloses that stinging nettle is conventionally included in a composition for treatment of allergic rhinitis. Prior art

reference to Bryce-Smith teaches that zinc is a simple, cheap and efficient treatment for an allergic condition. See the abstract.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine stinging nettle and zinc with other conventional allergy treating drugs including other antihistamines as well as conventional decongestants. "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

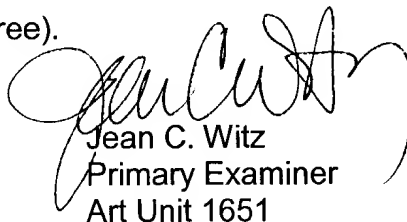
Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jean C. Witz whose telephone number is (571) 272-0927. The examiner can normally be reached on 6:30 a.m. to 4:00 p.m. M-Th and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jean C. Witz  
Primary Examiner  
Art Unit 1651